



MAIL STOP APPEAL BRIEF-PATENTS  
Docket No. 0508-1105  
PATENTS

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE  
THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Filippo BELARDELLI et al. Conf. 1462

Serial No. 09/845,042 Appeal No. \_\_\_\_\_

Filed April 27, 2001 Group 1644

METHOD FOR GENERATING HIGHLY ACTIVE HUMAN DENDRITIC  
CELLS FROM MONOCYTES

REPLY BRIEF

MAY IT PLEASE YOUR HONORS:

The non-enablement rejections having been withdrawn in the Examiner's Answer, the only issue remaining on appeal is whether any of the following recitations are new matter:

- i) within three days (claims 63, 69 and 72-76);
- ii) for a maximum of three days (claims 54, 63, 69 and 72);
- iii) collecting cells within three days (claim 69);
- iv) 500-1,000 IU/ml (claims 61, 63 and 71);
- v) 500-10,000 IU/ml (claims 57, 63 and 70); and
- vi) in the absence of IL-4 (claims 54, 63 and 69).

As to "within three days", the Examiner's Answer acknowledges that this phrase finds explicit antecedent basis in the specification (Examiner's Answer, page 5, last paragraph). The position of the Examiner's Answer appears to be that the recitation is not recited a sufficient number of times in the specification.

However, the specification teaches at page 5, lines 19-23, in the general characterization of the invention, that an advantage of the "process of the invention is that it provides a particularly rapid procedure for DC production which can be carried out in a brief period of time (within three days of culture)." The recitation of "within three days" therefore plainly does not introduce new matter into the disclosure.

The same result obtains for the phrases "for a maximum of three days" and "collecting cells within three days." In that a three-day culture is mentioned repeatedly throughout the specification, for example at page 9, lines 29 and 32-33; page 10, lines 3 and 20; page 11, line 20; page 12, lines 1, 7, 22 and 29-30; page 14, line 1; page 15, lines 12-13; page 18, lines 16-18 and 19-20; page 26, lines 6-8 and page 28, line 30, the phrases "for a maximum of three days," and "collecting cells within three days" is plainly supported by the specification.

While the exact ranges "500-1,000 IU/ml" of GM-CSF and "500-10,000 IU/ml" of type I IFN are not recited *ipsis verbis* in the specification, the end points for each range are explicitly recited (e.g., see page 6, lines 8-12; page 5, lines 33-34; and page 10, lines 19-20). As such, *In re Wertheim* is controlling. Indeed, in citing to MPEP §2163.05, the Examiner's Answer apparently overlooks the MPEP's explicit recognition of *In re Wertheim* and the passage stating, "with respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure". In that the end points for each range

are explicitly recited, one skilled in the art would plainly consider the ranges inherently supported by the specification.

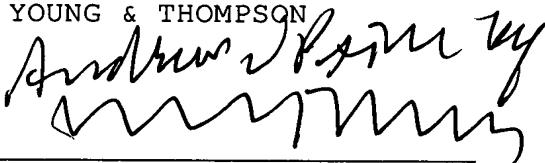
As to the recitation "in the absence of IL-4," in the specification, dendritic cells prepared in the presence of IFN and GM-CSF are repeatedly compared to dendritic cells prepared in the presence of IL-4 and GM-CSF (e.g., see page 19, lines 14-20; pg. 21, lines 23-26; pg. 26, lines 5-15; examples; and figures). Page 26, lines 6-7 makes it particularly clear in its reference to cells treated "either with IFN/GM-CSF [the invention] or IL-4/GM-CSF [the comparative examples]." It is therefore clear that the process of the invention is performed in the absence of IL-4.

The above discussion is believed to underscore that none of the phrases in question is new matter, and that this sole remaining ground of rejection should therefore be reversed.

Respectfully submitted,

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August 29, 2007